

## EXHIBIT 393

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**DEA Comments from the 6-04-08 Meeting on Suspicious orders**

DEA Attendees: D. Linden Barber, Associate Chief Counsel, Diversion and Regulatory Litigation Section; Office of the Deputy Assistant Administrator; Cathy Gallagher, Deputy, Liaison and Policy Section; Robert C. (Chris) Gleason, Deputy Chief Counsel

HDMA Attendees: Robert Barnett, Richard Cooper, (Williams & Connolly LLP); Anita Ducca, Scott Melville (HDMA); David Durkin (Olsson Frank Weeda Terman Bode Matz)

**P. 2 – Middle paragraph under “History”**

Change 1405 to 1316. Also 1301.71(a) deals with physical security. DEA recommends referring to section 823(b) and (d) of the statute, which provides the broader authority for preventing diversion in the supply channel.

**P. 3 - Outline**

DEA thinks the outline contains the necessary elements.

Recommended that we add into the outline that once an order is determined to be “suspicious” it shouldn’t be shipped. Noted that they observed it in the body of the Guidelines, but would like to see it up front, as well. To accommodate this point, we would need to add to the body of the document a stop-shipment heading, which would then be added to the outline.

**P.4 -- Item I.b.**

DEA was pleased to see that the questionnaire would be notarized or provided with the statement declaring that it is true and correct. DEA does not want changes but wants us to be aware that merely obtaining a signed document isn’t going to be enough of a “defense”. Distributors will have to do more to identify the ~~pharmacy’s~~ legitimacy.

**P.4 -- last tick mark on the page under the “information gathering step would include”**

There was some discussion of whether pharmacies know if their purchasers are doing internet business. DEA gave an example of fax prescriptions coming into pharmacies that appear legitimate but may not be. DEA suggests that we add a question to this list indicating that the distributor should ask pharmacies what they are doing to verify where the Rx is being generated. They suggested that the dispenser should focus on, among other things, the geographic locations of the patient, the prescribing physician, and the source of the fax. They suggest language similar to the following.

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How does the dispenser fulfill its corresponding responsibility to ensure that the prescriptions they receive are issued for a legitimate medical purpose (as described in 21 CFR 1306.04).

**P.5 – Next to last tick mark before (c)**

DEA doesn't routinely perform pharmacy audits. They suggest changing the wording to ask whether the pharmacy has been inspected by DEA, and, if so, why. Also suggested adding in a similar question about being inspected by the state Board of Pharmacy.

**P.5 – Independent investigations, 1<sup>st</sup> bullet**

DEA commented that they wanted us to be aware that they may not be able to share sensitive information. (But did not request changing this.)

**P.6 – First bullet regarding conducting Internet searches**

DEA felt this was a key point and was really glad we had included it. (No change requested)

**P.6 – Second bullet under Additional Recommendations and Documentation**

DEA also liked this point and was very glad to see that the questionnaires would be updated. (No change requested) Several times, they said that the procedures used by members should be "robust and adaptable." We may want to include that phrase in the document. They also noted that combinations of drugs used for abuse change over time, and said that members should be alert to such changes in examining families of drugs in orders.

**P.6 – II Monitoring for Suspicious Orders**

DEA commented generally that an electronic system alone is not enough, we can't rely solely on a computer system. There was some discussion of this, as DEA was looking for more but didn't really clarify what that would mean or what they expected. HDMA suggested it might be possible to do this by periodic auditing. DEA seemed to want something else done, that was not after-the-fact, that was not electronic, and that would identify problems very quickly, as the orders occurred. We explained the problems with this when there was rapid, over-night ordering/delivery of large volumes of products. No further suggestions came from DEA. HDMA agreed to look at it again.

DEA seemed to think that "thresholds" focus principally on volumes, and they expressed the view that an exclusive or even principal focus on volumes is inadequate. They also want the initial screen of orders to focus on (a) patterns of ordering (comparing the present order to (i) past orders from the same customer (including whether the frequency of orders is suspicious), (ii) orders from similar customers, and (iii) orders from other establishments of the same type in the locale or region), and on (b) combinations of controlled substances ordered. If sophisticated electronic screening can deploy algorithms to address such factors, we might be able to persuade DEA that an initial electronic screen is adequate.

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Another comment was that the term "Order of Interest" did not have legal standing. DEA recognized that there needed to be something in between finding an order that was questionable and one that was "suspicious". DEA did not object to our use of that term. They emphasized, however, that orders should not remain in the "order of interest" category for lengthy periods; they should be investigated expeditiously and promptly resolved as either suspicious or not suspicious.

**P. 6-8 Thresholds (General Comments)**

DEA felt that we should define "threshold" more carefully. They thought it might be interpreted to mean excessive volumes only. HDMA explained that our intent was to be broader for example to include "frequency" as a factor in calculating thresholds or "combinations" of orders of several different drugs.

DEA asked that we expand the explanation of thresholds.

DEA also asked that the document state that

The drug or drugs that cause an order to be an order of interest should not be shipped while the order is an order of interest.

DEA suggested that we delete the second paragraph under "c. Develop "Thresholds to Identify Orders of Interest". DEA has backed away from the standard of three times the monthly overage order for schedule II and ARCOS reportable schedule III products. DEA suggested that we substitute a paragraph based on more recent DEA guidance.

Cathy Gallagher stated they would send us copies of letters they had sent to pharmacies and distributors regarding how to look out for internet diversion. They felt that these might explain what to look for.

In the last paragraph on page 7, after the sentence "Thus, a single and/or national threshold may no longer be appropriate," it was suggested that we might insert a suggestion that members periodically check with their local DEA office re drug trend information and emerging local or regional concerns; and they might periodically check DEA's drug diversion website.

**P.8 – 3<sup>rd</sup> bullet under "Distributors are encouraged to consider . . ." and d. Cumulative Reviews/Thresholds**

DEA felt these were key concepts and asked if we could give them greater emphasis. DEA urged that the document explaining that a threshold in terms of volume alone is not enough, and these points helped clarify that there is more to determining thresholds than volume. They talked about the importance of evaluating groups of drug orders and other

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anomalies. They gave the example of an Internet Pharmacy that may be ordering from multiple distributors and that who might not order enough to go over a threshold over a period of time, but could be identified by a pattern of how and when they ordered. For example, they thought if a pharmacy ordered only every 3-4 months but then, when they did so, ordered a large volume, that might be a signal the pharmacy was doing business with several distributors and rotating which one who they ordered from.

HDMA noted that the 3<sup>rd</sup> bullet on the next page was intended to identify that kind of problem, but DEA felt that should be included in determining when a threshold was reached, not just in an after the fact review. HDMA said we would look at it again.

DEA also asked us to emphasize in paragraph "d" the recommendation to conduct periodic reviews of cumulative orders from the same customer, to evaluate trends in purchasing patterns.

#### **P.8 – Stop shipments of an order of interest**

DEA asked us to reemphasize that the order should not be shipped if there was reason to believe there was a problem.

In fact, they asked us to add in that if one controlled substance in the order could be a problem, then other controlled substances in the order may also be a problem and the distributor should consider holding the others. They gave the example of an order where the volume of hydrocodone triggered a threshold but that both hydrocodone and alprezolam (sp?) were included in the same order. If hydrocodone triggered the threshold but alprezolam did not, under our ICG's, the hydrocodone shipment would be held but the alprezolam would not. They felt that the alprezolam order might also be suspect. If one part was suspicious, wouldn't all of it be suspicious?

We explained that frequently the distributors knew the customer and their business and wouldn't feel that their order was unusual and wouldn't want to hold the alprezolam in that instance.

DEA understood but still felt that it should be pointed out in the ICG.

In general, DEA did not object to our recommendation that the particular drug or drugs that cause an order to be an order of interest (or a suspicious order) should not be shipped, but other drugs can be. Their point was that, in some circumstances, the connection between that drug and another drug in the order should lead the wholesaler not to ship the other drug as well. Again, in their view, looking a volume ordered drug by drug is not enough; and basing thresholds solely on volume(s) is not enough. Even an order for a drug that does not meet a volume threshold may be suspicious in light of other aspects of the order.

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#### **P.9 Investigating the Order**

DEA requested that we add an underlined heading a bullet point that the distributor should compare that pharmacy's order [that triggered the threshold] to other pharmacies of the same type or practice area.

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Re the third bullet, DEA emphasized that a pattern of a large order one month, followed by several months of no order, followed by a month with a large order warrants investigation. There may be an innocent explanation, or there may not be.

**P. 10 2<sup>nd</sup> Bullet**

DEA noted that if we include a provision to call DEA to verify information DEA staff would need to alert their regional offices to expect such calls. They did not object to our including it; they merely noted that they would need to ask the field offices to document the calls they receive from pharmacies, etc., so that they don't give our members incorrect information (e.g., "we have no record of such a call from your prospective customer").

**P. 11, paragraph "a".**

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DEA asked us to emphasize that suspicious orders must be reported to DEA whether the wholesaler ships or not, and to emphasize that the timeliness of notice is very important.

**P. 12 VI Additional Recommendations- Third Bullet**

DEA asked us to either expand this bullet or create a new bullet to highlight that the distributor's own experience may indicate a need to ~~reverse~~ their system for S.O. monitoring. Although DEA did not explicitly state so, they were pretty clear that they would like to see some distributor- specific information examples added to the government ones.

**Additional Comments/ Points Raised**

- DEA was emphatic that if there were questions about an order, the order should not be shipped.
- They wanted reports on all "suspicious orders" even if the order was not shipped.
- Timeliness is very important. DEA wants us to emphasize the need for rapid, timely reporting.
- DEA wants reports of "suspicious orders" even if there is some question about the dispenser's status as a customer. For example, if during a background check of a potential customer, the customer indicates they might be placing orders that could be "suspicious", DEA wants to know, even if the pharmacy in question, does not become a customer.
- For several of DEA's suggestions, Cathy Gallagher is going to research whether DEA may have some additional guidances.

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